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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/180,209	12/22/1999	MIHAIL N. KARPUSAS	B189	6529

7590

09/22/2005

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/180,209

Applicant(s)

KARPUSAS ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/27/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39,42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39,42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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Claims 39 and 42-43 are pending. The arguments and SINGH declaration filed 6/27/05 have been fully considered but are not persuasive. Responses to the arguments are set forth below.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 39 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over MANDEL et al. (US 6,703,486)

MANDEL teaches a computer for producing a three dimensional representation of binding and active sites of a protein (Fig. 12 and col. 3, lines 39-47). MANDEL teaches that his computer may comprise a variety of programs for 3D modeling based on atomic or X-ray coordinates (col. 25, line 27-col. 26, line 25), teaches that his data may be carried on computer-readable media (col. 23, lines 25-40), and teaches a monitor for displaying results (col. 25, lines 16-18).

The arguments set forth in the response refer to and are duplicative of those in the SINGH declaration are similar, thus the arguments are addressed as a group below.

In response to the repeated argument that the structure coordinates are functional descriptive material, the examiner maintains that the coordinates themselves do not functionally interact with either the computer nor the program such that the computer or program, or the actual coordinates, are changed or transformed.

Passages from the MPEP are reiterated below with emphasis added by the examiner:

MPEP 2106.II.B.1

(b) Nonfunctional Descriptive Material

Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided.

Where certain types of descriptive material, such as music, literature, art, photographs and **mere arrangements or compilations of facts or data**, are merely stored so as to be read or outputted by a computer **without creating any functional interrelationship**, either as part of the stored data or as part of the computing processes performed by the computer, **then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.**

Such "descriptive material" is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).)

The policy that precludes the patenting of nonfunctional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an

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article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for nonfunctional descriptive material. The purely nonfunctional descriptive material cannot alone provide the practical application for the manufacture.

MPEP 2106.IV

Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. > In re Ngai, ___ F.3d ___, 2004 WL 1068957 (Fed. Cir. May 13, 2004).< Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- **a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or**
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

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Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of nonfunctional descriptive material.

Thus, contrary to applicant's arguments that the structural data is NOT similar to a compilation of music, it is noted that the "ability" of the claimed computer to display a 3D representation is similar to the "ability" of that same computer to play music encoded on a CD. In each case, the computer comprises a program which instructs the computer to read data from a computer readable medium and to output the data in a particular format. In neither case does the data change either the instructions or the computer itself. Nor is the data changed by the computer or program; both the data set or coordinates and the music on the CD remain the same. Upon removal of the computer readable medium, neither the computer nor the program which resides therein becomes a structurally or functionally different entity. In fact, it is well known in the art that programs for displaying and manipulating crystal coordinate data, such as DOCK, Insight and QUANTA, were designed to be, and are, capable of modeling ANY set of data presented in the proper format. It is noted that the program claimed is not limited to be any particular program, but is merely one with instructions to produce a three dimensional representation of data. Whether the data is "new" or "novel" and "specific", as argued by applicant, does not alter the instructions themselves.

The argument that the computer and program are functionally changed by the structure coordinates is perplexing to the examiner, as no *functional* change is described by applicant. The difference in the program instructions and/or physical computer components caused by the structure coordinates residing on the computer readable medium is not elucidated anywhere.

In response to the argument that the computer is one capable of use in methods of *in silico* drug design is certainly intriguing; however, the claims are not directed to a method of drug design or discovery. No steps of using the claimed coordinates “as a scaffold for use in drug design targeting” are recited anywhere in the claims. It is noted that all of the pending claims are directed to computers, not to methods of use. The apparent argument that the program is one for “dynamic” three-dimensional representation is not persuasive as the claimed program is not so limited. There are no limitations, program instructions or method steps recited which would result in mutation of side-chains, alteration of bond lengths or angles, interactive calculation of distances, docking, or energy minimization recited anywhere in the pending claims.

In response to the argument that structure coordinates integrated on computers are crucial to modern-day drug design, it is noted that structure coordinates stored or otherwise “integrated” on computers have long been recognized as being useful, as evidenced by the inception of the Protein Data Bank in 1972. The rejection herein, however, is not one of utility or enablement (i.e. how to “use”), but of obviousness. It is noted that those of skill in the art do not consider the addition of particular structure coordinates to the PDB to be a change which causes the PDB to become a different

entity; i.e. wherein the new coordinates cause a functional change in the computer on which the database is stored.

For all of the reasons set forth above, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
9/15/05